

### **REMARKS**

This is in response to the FINAL Office Action dated October 24, 2012. Reconsideration in view of the following is respectfully requested.

### **Claim Status**

Claims 12-15 and 25-35 are pending in the application. Claims 25-35 stand rejected. Claims 1-11, 16-24, and 36-38 were cancelled.

### **Amendments in compliance with 37 CFR § 1.116(b)(1)&(3)**

Applicants would like to stress that the amendments fully comply with all requirements expressly set forth in the present or previous Office action, by correction/amendment as requested/suggested by the Examiner, or by cancelling the relevant rejected claims.

Notably, the Examiner's rejections responded to in the amendments relate to essentially formal issues only, even though they correspond to rejection under 35 USC § 112; in particular: antecedent basis, incorrect plural s, Markush language or vagueness.

Further amendments by the Applicants relate to minor changes to correct further informalities.

These amendments are thus necessary to remove the informalities.

Since the amendments merely correct informalities, adopt the examiner's suggestions, or make minor changes, all of which require no more than a cursory review by the Examiner, they are thus not believed to require a stringent showing of timeliness.

In view of the foregoing, and because this amendment is believed to place the application in condition for immediate allowance, or, if not, at least in a better form for a possible appeal, Applicants respectfully request that the Examiner enter and consider this amendment.

**Claim Amendments:**

- Claims 25 & 29: Deleted “the” to correct the objected-to lack of antecedent basis, as requested.
- Claim 29: Corrected “Antibody” to “Antibodies”, consistent with “the antibodies” later recited in the plural in the same claim.
- Claim 30: Deleted the objected-to plural term (“isoenzymes”) by specifying elastase as “elastase 1” (thus removing the need for the term “isoenzyme(s)), as requested. Notably the recited peptides correspond to elastase 1.
- Corrected “one or more different antibodies” to “two or more different”.
- Claim 33: Corrected antecedent basis (“two or more different ... antibodies specific for ... elastase 1”, as recited in claim 30), as requested;
- Deleted objected-to term “suitable detection system”, as requested, and replaced the objected-to wording relating to the two antibodies relationships/function with the Examiner’s earlier suggestion.
- Claim 34: Inserted “consisting”, to correct the objected-to incomplete Markush group phrase, as requested.
- Corrected “one or more different antibodies” to “two or more different”.
- Corrected “elastase” to “elastase 1”, consistent with claim 30.
- Notably the recited peptides correspond to elastase 1.
- Claims 36&38: Cancelled.

The claim amendments find support as indicated previously in the response of May 31, 2012, and do not introduce new matter.

**Examiner's item 1 - Missing status of prior applications**

**Objection to the Specification**

As requested, a reference to the prior filed applications and the relationship of the applications has been included in the first paragraph following the title on page 1 of the present specification, see Amendment to the Specification above.

**Examiner's item 2 - Plural s in "isoenzymes"**

**Claim Rejections - 35 USC § 112 1st paragraph, Claims 30-33 and 36-38**

The Examiner rejects the claims as lacking written description/enablement because they recite a plural of elastase iso-enzymes.

Claim 30 has been amended without prejudice, deleting "isoenzyme(s)", and elastase has been specified as "elastase 1" (according to the specificity of the claimed peptides of SEQ ID 2, 3, 4 and 5), thus obviating the rejection.

Claim 32 depends on claim 30 and does not recite isoenzyme(s). The above amendment to claim 30 obviates the rejection to claim 32.

Claim 33 has been amended without prejudice, deleting "isoenzyme(s)" and correctly specifying the antibodies for proper antecedent basis as recited in claim 30 which claim 33 depends on, thus obviating the rejection.

Claims 36-38 have been cancelled without prejudice, obviating their rejection.

Reconsideration of the rejection is respectfully requested.

**Examiner's item 3 -**

**Superfluous or missing "the"/ "consisting", antibody passage in cl. 33 & dependent claims;**

**Claim Rejections - 35 U.S.C. § 112, 2nd paragraph/Indefiniteness, Claims 25-38**

***Claim 25&29 & dependent claims:***

The Examiner objected to the lack of antecedent basis of "the formation".

"the" [formation] has been deleted, thus obviating the lack of antecedent basis issue.

***Claim 30&dependent claims:***

The Examiner objected to the “identification” or determination of amounts of a plurality of isoenzymes.

Elastase has been specified as “Elastase 1”, “identification” has been deleted, and the term “isoenzyme(s)” has been deleted, thus obviating the rejection.

***Claim 33:***

The objected-to “suitable detection system” has been deleted. The claim wording with regard to the interrelationships and function of the two different antibodies has been adjusted to the wording suggested earlier by the Examiner, thus obviating the rejection.

***Claim 34:***

The Examiner objected to improper Markush group language which has been corrected inserting “consisting”, thus obviating the rejection.

***Claims 36-38:***

These claims have been cancelled, obviating their rejection.

Reconsideration of the rejection is respectfully requested.

**Examiner’s item 4 - missing “the” (antibodies)**

**Claim Rejections - 35 U.S.C. § 112, 4th paragraph, Claims 33, 36-38**

The Examiner rejected the claims for being in improper dependent form/including all limitations because they did not appear to require the antibodies of claim 30/did not recite “the” (antibodies).

***Claim 33*** has been corrected inserting the missing “the”, thus rendering the claims in proper dependent form and obviating the rejection, as suggested by the Examiner (“Applicant may amend the claims(s) to place the claim(s) in proper dependent form”).

**Claims 36-38** have been cancelled, thus obviating their rejection, as suggested by the Examiner (“Applicant may cancel”).

### **Prior Art**

In response to Examiner’s assertions with regard to the prior art on page 6-8 of the Office Action, for the sake of brevity, Applicants make reference to the earlier remarks in the Applicants’ previous response, including those relating to the legal standard of inherency; as discussed therein in more detail, the claimed subject matter is not inherently present in a random preparation of purified or fragmented elastase enzyme.

### **Request of a telephonic interview with the Examiner**

Applicants hereby request a telephonic interview to discuss remaining issues, if any.

### **CONCLUSION**

The instant application is believed to be in condition for allowance. A Notice of Allowance for the claims is respectfully requested. The Examiner is invited to telephone the undersigned at (212) 808-0700 if it is believed that further discussions, and/or additional amendment would help advance the prosecution of the instant application.

### **CONDITIONAL PETITION FOR EXTENSION OF TIME**

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

### **ADDITIONAL FEE**

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

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Response of January 23, 2013 to FINAL Office Action of October 24, 2012

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Early and favorable action is earnestly solicited.

Respectfully submitted,

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